REMARKS

This paper is a Response to the final Office Action mailed January 11, 2010. Claims 6, 9 and 12 to 15 are under consideration.

I. REJECTION UNDER 35 U.S.C. §101

The rejection of claims 6, 9 and 12 to 15 under 35 U.S.C. §101, as allegedly lacking utility is respectfully traversed. The rejection set forth in the Office Action, pages 2-5 alleges that SEQ ID NO:50 and 72 in combination, with or without SEQ ID NO:84, does not have nitrile hydratase activity.

Claims 6, 9 and 12 to 15 have utility under 35 U.S.C. §101. Applicants respectfully point out that the specification discloses that SEQ ID NO:50 and 72 in combination has nitrile hydratase activity (see page 25, Table 1). In particular, M49bD9 contains the genes for α and β subunits, SEQ ID NOs:49 and 71 respectively (page 25, lines 5-8). The α and β subunit genes, SEQ ID NOs:49 and 71 respectively, encode the α and β subunit proteins denoted SEQ ID NOs:50 and 72, respectively. As disclosed in Table 1, clone M49bD9 has nitrile hydratase activity without P12k (30 U/g of dry biomass (DBM)), and with P12k gene (SEQ ID NO:83; 826 U/g of dry biomass (DBM)). Thus, in view of the specification, the combination of α and β subunit proteins SEQ ID NOs:50 and 72 has nitrile hydratase activity with and without p12K. Consequently, as the combination of SEQ ID NOs:50 and 72 has nitrile hydratase activity, claims 6, 9 and 12 to 15 have utility under 35 U.S.C. §101.

II. REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

The rejection of claims 6, 9 and 12 to 15 under 35 U.S.C. §112, first paragraph, as allegedly lacking an adequate written description and enablement is respectfully traversed. It appears that this rejection in the Office Action, pages 5-6, is due to SEQ ID NO:50 and 72 in combination, with or without SEQ ID NO:84, allegedly lacking nitrile hydratase activity.

As discussed above, the specification discloses that the combination of SEQ ID NO:50 and 72 has nitrile hydratase activity with and without P12k (see page 25, Table 1). In particular, M49bD9 genes for α and β subunit, SEQ ID NOs:49 and 71, respectively, encode the α and β subunit proteins denoted SEQ ID NOs:50 and 72. As disclosed in Table 1, clone M49bD9 has nitrile hydratase activity without P12k (30 U/g of DBM), and with P12k gene (SEQ ID NO:83; 826 U/g of DBM). Thus, in view of the specification, the combination of α and β subunit proteins SEQ ID NOs:50 and 72 has nitrile hydratase activity with and without

p12K. Consequently, the grounds for rejection under 35 U.S.C. §112, first paragraph, as allegedly lacking an adequate written description, is moot.

Applicants also respectfully reiterate that as discussed in the record, a proper analysis for written description under 35 U.S.C. §112, first paragraph is whether one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991); see, also, *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985). Here, for the reasons of record, namely that the claims specify both a structure and a function, and in view of the guidance in the specification, which discloses numerous sequences of nitrile hydratase α and β subunits, and the knowledge in the art regarding conserved sequence motifs of nitrile hydratase α and β subunits, the skilled artisan would be apprised of an adequate number of nitrile hydratase α and β subunits within the genus of claims 6, 9 and 12 to 15.

In particular, the specification teaches 12 nitrile hydratase α subunits and 10 nitrile hydratase β subunits. Sequences having 90% or more identity to the recited sequences will share a high degree of sequence identity, and in view of the knowledge in the art concerning nitrile hydratase α and β subunit structure and function, one skilled in the art would know functional nitrile hydratase α and β subunit sequences having the specified 90% or more identity. For example, nitrile hydratase α subunits are characterized by a conserved motif, namely CXXCSC. This motif, which is present in all nitrile hydratase α subunits, coordinates a cobalt and iron ions for catalytic activity. Nitrile hydratase β subunits are also characterized by a conserved motif, namely D-X-[G/A]-G at the N-terminus. A version of this conserved sequence motif, namely D-[M/L/I]-G-G is in all nitrile hydratase β subunits disclosed in the application.

Thus, in view of the guidance of the specification which teaches numerous nitrile hydratase α and β subunit sequences, and the 90% or more identity to specific nitrile hydratase α and β subunit sequences, when combined with the knowledge in the art concerning nitrile hydratase α and β subunit structure and function at the time of the invention, the skilled artisan would know a variety of nitrile hydratase α and β subunit sequences with 90% or more identity to the recited sequences that would retain at least partial nitrile hydratase activity. Consequently, the skilled artisan would be apprised of a number of nitrile hydratase α and β subunits within the scope of the claims.

In sum, the skilled artisan would be apprised of an adequate number of nitrile hydratase α subunits and β subunits within the claimed genus in view of the fact that the

specification discloses several nitrile hydratase α and β subunit sequences, that sequences with 90% or more identity to the recited sequences share significant identity, and the knowledge in the art regarding the structural motifs for nitrile hydratase α and β subunit activity. As such, the written description requirement under 35 U.S.C. §112, first paragraph is satisfied here, and Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph as allegedly lacking an adequate written description be withdrawn.

In summary, for the reasons set forth herein, Applicants maintain that the claims clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 509-4065. Please charge any fees associated with the submission of this paper to Deposit Account Number 033975. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,

PILLSBURY WINTHROP SHAW PITTMAN LLP

ROBERT M. BEDGOOD, Ph.D.
Reg. No. 43488
Tel. No. 858.509.4065
Fax No. 858 509.4010

Date: May 7, 2010
12255 El Camino Real, Suite 300
San Diego, CA 92130-4088
(619) 234-5000